

**R E M A R K S**

This paper is being filed in response to the Office Action dated July 15, 2003 that was issued in connection with the above-identified patent application. Applicants also enclose herewith a Petition for a three-month Extension of Time pursuant to 37 C.F.R. §1.136(a) and the fee required under 37 C.F.R. §1.17(a)(3). Applicants respectfully request reconsideration of the instant application in view of the amendments and remarks presented herein.

Claims 1-65 are pending in the instant application. Applicants have previously elected claims 1 and 8-41 for prosecution in the present case. Thus, claims 2-7 and 42-65 have been canceled without prejudice to or disclaimer of the claimed subject matter. Applicants expressly reserve the right to pursue the subject matter of the non-elected claims in one or more further applications.

Claims 1, 27-34, 38, and 40 have been amended to correct typographical and minor clerical errors and expand abbreviations. In addition, claim 34 has been amended to recite SEQ ID NOS:4-12. Applicants assert, therefore, that these amendments are fully supported by the application as filed and do not constitute new matter. Specification paragraphs [0009], [0046], and [0052] have been amended to expand abbreviations. These amendments are fully supported by the application as filed and, therefore, do not constitute new matter.

**Objections Rendered Moot by Amendments Herein**

Objections to the specification have been made for informalities. Applicants assert that the specification has been amended accordingly (*e.g.* to expand abbreviations) rendering these objections moot.

Claim 29 has been objected to for reciting an abbreviation. Applicants have amended claim 29 to recite a “lentiviral lytic peptide-1” and, therefore, respectfully request withdrawal of this objection.

Claims 29-34 have been objected to for reciting “An LLP-1 peptide....” The Examiner has alleged that “An” should be replaced with “A”. Applicants have amended claims 29-34 to recite “An isolated and purified lentiviral lytic polypeptide-1....” Therefore, Applicants respectfully request withdrawal of this objection.

**Claims Are Drawn to Statutory Subject Matter**

Claims 1, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26-34, and 38-39 have been rejected under 35 U.S.C. §101 as allegedly reciting nonpatentable naturally existing peptides and proteins. The Examiner has alleged that claims 1 and 26 (*sic*, 29?) and their dependents do not distinguish over naturally-occurring polypeptides, proteins and enzymes. In response to the Examiner's suggestion, Applicants have amended claims 1 and 29-34 to recite “isolated and purified” to distinguish over "products of nature" and, therefore, respectfully request withdrawal of this rejection.

**Claims Are Clear and Definite**

Claims 29-34 and 38-39 have been rejected under 35 U.S.C. §112, second paragraph for reciting terms that are allegedly indefinite. The Examiner has alleged that the term “LLP-1 peptide” is unclear in whether or not it refers to the tripeptide Leu-Leu-Pro.

Applicants respectfully disagree and assert that it would be abundantly clear to an artisan of ordinary skill that “LLP-1” refers to lentiviral lytic peptide 1 in view of the explicit definition as such in the specification. Specifically, at page 4, paragraph [0005], for example, the application states:

These peptides are referred to as lentiviral lytic peptides (LLPs) with the prototypical LLP being LLP1 (amino acids 828-856 of the HIV-1 viral isolate HXB2R Env). LLP1 is derived from the 28-residues encoded by the C-terminal portion of the HIV-1 TM protein that, when modeled as an  $\alpha$ -helix, demonstrates amphipathic character with clearly delineated cationic and hydrophobic faces.

Applicants are permitted to be their own lexicographer. *See e.g.* MPEP §2173.01. Although Applicants acknowledge that the three letters “LLP”, in other contexts, may represent the single letter amino acid code for a Leu-Leu-Pro tripeptide, this meaning is precluded here in view of the foregoing explicit definition. Moreover, the very presence of a hyphen and the numeral “1” would indicate a meaning other than Leu-Leu-Pro to the artisan of ordinary skill.

Nevertheless, solely in view of the objection to claims 29-34 for reciting abbreviations, Applicants have amended these claims to expand the term “LLP-1” to “lentiviral lytic peptide-1,” thereby obviating this rejection. This amendment expanding the abbreviation LLP-1 does not in any way narrow the scope of the claims nor is it intended to constitute a surrender of any subject matter. Applicants further assert that it is made in response to an objection, not a rejection and, therefore, is being made for a reason unrelated to patentability. Therefore, Applicants respectfully request withdrawal of this rejection.

Claim 34 also has been rejected under 35 U.S.C. §112, second paragraph for reciting “additional residues.” The Examiner has alleged that it is unclear to which amino acids these “additional” amino acids are compared. Applicants traverse this rejection and assert that claim 34, as amended herein to recite SEQ ID NOS:4-12, is clear and definite. Therefore, Applicants respectfully request withdrawal of this rejection.

Claim 38 also has been rejected under 35 U.S.C. §112, second paragraph for reciting “at least one cysteine residue.” According to the Examiner, this is unclear because the peptides of claim 1 allegedly do not contain cysteine. Likewise, claim 39 has been rejected for

reciting “a disulfide-linked dimeric peptide.” Regarding claim 39, the Examiner has further alleged that it is unclear whether the term “dimeric” refers to heterodimers, homodimers, or both.

Applicants traverse these rejections and assert that claim 38, as amended herein to recite “wherein said peptide further comprises at least one cysteine residue,” is clear and definite. Applicants further assert that the term “dimeric” should be given its “broadest reasonable interpretation consistent with the specification.” *See MPEP § 2173.05(a).* One of ordinary skill in the art would recognize that the term “dimer” includes both heterodimers and homodimers. While the specification offers examples of homodimers at paragraph [0007] and [0039], it does not modify or limit this definition. Therefore, it would be clear to one of ordinary skill in the art that both heterodimers and homodimers are contemplated by the term “dimeric” in claim 38. Accordingly, Applicants respectfully request withdrawal of these rejections.

#### **Claims Are Supported by an Adequate Written Description**

Claims 29-34 have been rejected under 35 U.S.C. §112, first paragraph for containing subject matter that allegedly lacked adequate written description in the specification to convey to one of ordinary skill in the art that applicants were in possession of the invention. While the examiner has acknowledged that the applicants were in possession of antimicrobial peptides of SEQ ID NOS:4-12, the examiner has alleged that applicants are not in possession of any analogs of lentiviral lytic peptides. The examiner has alleged that there is insufficient description about how to make bioactive variants.

Applicants traverse this rejection and assert that the specification provides substantial teaching demonstrating that Applicants were in possession of LLP-1 analogs as claimed.

According to the "PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, 'Written Description' Requirement" (hereinafter "WD Guidelines"). See 66 Fed. Reg. 1099 (2001), the written description requirement may be satisfied by disclosing (a) identifying **structural**, physical, and/or chemical properties, (b) identifying functional characteristics coupled with the **correlation between structure and function**, (c) a combination of (a) and (b). See *Id.* at 1106. Applicants assert that this application satisfies **both** (a) and (b).

For example, Applicants respectfully invite the Examiner's attention to paragraphs [0037] and [0038] defining the **structural** features of these analogs. The application, as the Examiner has acknowledged, provides the formulae, *i.e.* the amino acid sequence, of **nine** specific members of the claimed genus (Table 1). In addition, Applicant's specification discloses the **correlation between structure and function** at paragraphs [0004] and [0028]. The specification further provides general guidelines for preparing analogs (paragraph [0009]) including use of computer modeling (paragraph [0044]) and performing bioassays (paragraph [0046] *et seq.*). Therefore, LLP-1 peptide analogs are adequately described by Applicant's specification to demonstrate possession of the full scope of the claims.

### **Claims Are Not Unpatentable over the '058 Application**

Claims 1 and 8-41 have been provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as copending application No. 09/785,058 (hereinafter "the '058 application"). The Examiner has noted that this is a provisional rejection since the claims of the '058 application have not been patented.

Applicants enclose herewith a copy of a Letter of Express Abandonment that is being concurrently filed in connection with the '058 application (Exhibit 1). Applicants have reserved all rights to pursue the subject matter of the '058 application in one or more copending

applications (e.g. this application and any derivative applications). In view of the abandonment of the '058 application, Applicants respectfully request withdrawal of this rejection.

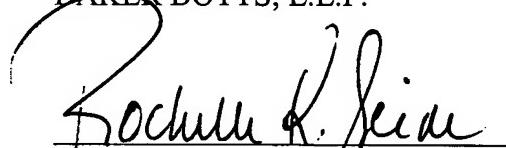
In conclusion, Applicants believe the claims of the instant application are in condition for allowance and earnestly request prompt favorable action.

Applicants enclose herewith the fee required under 37 C.F.R. § 1.17(a)(3).

Applicants do not believe that any additional fees are required with this paper. Nevertheless, the Commissioner is hereby authorized to charge any fees occasioned by this submission not otherwise enclosed herewith to Deposit Account No. 02-4377. Please credit any overpayment of fees associated with this filing to the above-identified deposit account.

Respectfully submitted,

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Enclosures